

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

TN

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/335,363

06/17/99

SHIBATA

G

39D-1884

IM22/0822

MARGARET A KIVINSKI
4300 N HARBOR BLVD
P O BOX 3100
FULLERTON CA 92834

EXAMINER

BEX, P

ART UNIT

PAPER NUMBER

1743

9

DATE MAILED:

08/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/335,363

Applicant(s)

SHIBATA ET AL.

Examiner

P. K. Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

1. The addition of claims 33-34 is acknowledged and has been entered into the record.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification does not support the limitation of immediate storage tube location with an associated alert mechanism for identifying when the immediate sample is loaded into the system, see claims 11 and 24. The specification does support error flagging when a sample identification is not stored in the DataLink Computer, see page 22, lines 4-7.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 20-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20, line 7, "it" is vague and indefinite as to what element it refers to.

Same line, "the sample identification station" lacks antecedent basis.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-11, 13-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Mazza et al* (USP 5,350,564) in view of *Kodama et al* (USP 6,117,683).

Mazza et al teach a automated analyzer system comprising a sample identification station for determining sample identification information, a carriage mechanism 16, 22 that transports sample tubes 28 with a bar code 30 to the sample identification station 234, a continuous transport mechanism 10 for moving the sample tubes within the system. Wherein, the continuous transport mechanism is a continuous belt 248 with a plurality of sample tube carriages 32 mounted on thereon. The sample tube carriages hold the sample tubes in place with resilient clips 258 and provide lateral access to the tube from at least two sides of the sample tube (Figs. 8-9). The system further comprising a plurality of tube transfer stations 48 adapted to move a sample tube from the continuous transport mechanism to an interface 42 of a plurality of analyzers 40, a controller "C" for receiving sample identification information and issuing a sample testing procedure (Figs. 1-10). Additionally, *Mazza et al* teach a bar code reader for reading sample identification information from the primary tube and a tube spinner for holding and spinning the primary sample tube 226, 180 (column 15, line 60- column 16, line32). *Mazza et al* fail to teach a probe or transferring mechanism that draws a volume of sample from a sample tube and

transfers the volume to a reaction tube. Kodama *et al* do teach a carriage mechanism 15b that grips a rack containing a plurality of primary sample tubes and transports the primary sample tubes to a sampling station 16b wherein, the sampling station includes a probe 204 that draws a volume of sample from a sample tube and transfers the volume to a reaction tubes in reaction conveyer 203. Moreover, Kodama *et al* teach an alert mechanism 33 for identifying when an immediate sample tray is loaded into the system (column 4, lines 28-40) and a control unit, 1, conveyance instructing unit and operation unit.

Accordingly, it would have obvious to one of ordinary skill in the art to modify the automatic analyzer of Mazza *et al* with those of Kodama *et al* at the time of the claimed invention. One skilled in the art would have recognized the benefits of using an intermediate sample probe to dispense sample to a plurality of reaction tubes, thereby reducing the amount of limited sample needed for analysis.

Regarding the specific location of the clips within the sample tube carriage, Mazza *et al* discloses the claimed invention except for the use of clips that engage the upper and lower portion of the sample tube. It would have been an obvious matter of design choice to include such use of clips. Moreover, since applicant has not disclosed that the location of the clips solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the clips taught by Mazza *et al*.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza *et al* (USP 5,350,564) and Kodama *et al* (USP 6,117,683) as applied to claim 10, and further in view of Kurosaki *et al* (USP 5,587,129).

Mazza *et al* and Kodama *et al* as discussed previously, fail to teach a sample probe comprising a cap piercer for removing liquid from the primary sample without removing the cap from the primary sample tube. However, the use of cap piercing probes is considered conventional in the art, see Kurosaki *et al*. Kurosaki *et al* teach an automatic analyzer which comprises a probe 12 for aspirating part of a sample from a sample tube 4 and dispensing into a reaction tubes 8 (column 3, line 62- column 4, line 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated in the system of Mazza *et al* and Kodama *et al* the piercing probe, as taught by Kurosaki *et al*, in order to aspirate the contents of the sample vial without exposing the sample to possible environmental contaminants.

Response to Arguments

9. Applicant's arguments filed June 29, 2001 have been fully considered but they are not persuasive. In response to the previous objection to the specification as failing to provide proper antecedent basis as recited in claims 11 and 24, Applicant points to a STAT button 38 that when manually pressed, alerts the system that there are sample tubes in STAT positions that must be accessed (page 11, lines 1-7). However, upon inspection of page 11, lines 1-7, Examiner could find no mention of an associated alert mechanism. The cited passages describe the gripper assembly. Therefore the rejection is maintained.

Regarding the rejection of claim 20-23 and 25-30 under 35 U.S.C 102(b) as being anticipated by Mazza *et al* (USP 5,350,564), Applicant states "The Examiner acknowledged that the Mazza reference failed to teach or suggest the claimed carriage mechanism". Examiner does not agree, but rather the previous Office Action states that Mazza *et al* fail to teach a carriage

mechanism that transports the primary sample tube to a sampling station, wherein the sampling station includes a sampling probe that draws a volume of sample from the primary tube and transfers the volume to a secondary tube. Clearly, Mazza *et al* do teach a carriage mechanism 16, 22, as previously pointed out.

Regarding the rejection of claims 1-11, 13-19 and 24 under 35 U.S.C. 103(a) as being unpatentable over Mazza *et al* (USP 5,350,564) in view of Kodama *et al* (USP 6,117,683), Applicant argues that Kodama has no teaching of moving an *individual* primary tube. Additionally, Applicant argues that the Kodama reference teaches a transfer mechanism for transferring racks holding a *plurality of vessels*. However, this argument is not germane to the issue since Applicant has not excluded such a feature from the claims. The claims are not restricted to moving a *single* individual tube. Additionally, Kodama *et al* do teach that the number of sample vessels contained in the sample rack is not limited (column 4, lines 21-24). Furthermore, Kodama *et al* is relied upon for the teaching of a *probe or transferring mechanism* that draws a volume of sample from a sample tube and transfers the volume to a reaction tube, not the carriage mechanism, see above Office Action.

Regarding, the previous rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Mazza *et al* (USP 5,350,564) and Kodama *et al* (USP 6,117,683) in further view of Kurosaki *et al* (USP 5,587,129), Kuroski does not teach a "carriage mechanism that grips one of the plurality of primary sample tubes". Examiner points out that Mazza *et al* is relied upon for teaching the carriage mechanism that grips one of the plurality of primary sample tubes and Kuroski *et al* is relied upon for the teaching of a cap piercing means. Examiner points out that one cannot show nonobviousness by attacking references individually where the

rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

10. No claims allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For official papers after mailing of a Final Office Action, use fax number (703) 305-3599. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Application/Control Number: 09/335,363

Page 8

Art Unit: 1743

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
8/20/01

Jill Warden

Jill Warden
Supervisory Patent Examiner
Technology Center 1700